K120578 (pg. 1 of 2)

MAR 2 9 2012

510(k) Summary of Safety and Effectiveness:
Accolade II Hip Stem

Proprietary Name: Accolade II Hip Stem

Common Name: Hip Prosthesis

Classification Name and Reference: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, 21 CFR §888.3353

Proposed Regulatory Class: Class II

Product Codes: 87MEH, 87LZO, 87LWJ, 87KWZ, 87KWY, 87KWL, 87JDI, 87LPH

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Date Prepared: 2/17/2012

Description:
The Accolade II Femoral Hip Stem, a tapered non-porous coated femoral stem intended for cementless, press-fit application. Accolade II has a variable medial curvature which increases with each stem size in order to facilitate press fit stability and load transmission in the proximal region of the femur. The stem geometry is designed to address variations in patient femoral morphology. The overall stem length has been reduced, compared to the Accolade TMZF hip stem, to facilitate intra-operative stem insertion.

The stem is manufactured from a Ti-6Al-4V substrate material, Commercially Pure (CP) Titanium coating and Purefix hydroxylapatite (HA) coating identical to the previously cleared 2 Piece Modular Hip Stem (K013106). The Accolade II Femoral Hip Stem is available in 12 sizes ranging from size 0 through 11 with two neck angles (127° and 132°) that provide dual head offsets. The stem is designed for use with the currently available compatible Howmedica Osteonics' femoral heads and their compatible acetabular components. The Accolade II Femoral Hip Stem is a sterile, single-use device intended for use in primary and revision total and hemi hip arthroplasty to alleviate pain and restore function. The subject hip stem is

compatible with V40 heads, C-taper heads when used with the V40/C-Taper Adaptor Sleeve, Universal Heads when used with the V40/Universal Adaptor Sleeve and Unitrax Heads.

Intended Use:
The modification does not alter the intended use of the predicate Accolade II system as cleared in the referenced premarket notifications.

Indications for Use:
The indications for use of the total hip replacement prostheses include:
1) Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2) Rheumatoid arthritis
3) Correction of functional deformity;
4) Revision procedures where other treatments or devices have failed; and,
5) Nonunions, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
Additional indication specific to use of Accolade II Femoral Stems with compatible Howmedica Osteonics Constrained Liners:
1. When the stem is to be used with compatible Howmedica Osteonics Constrained Liners, the device is intended for use in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability.
Accolade II Femoral Stems are intended for cementless use only and are intended for total and hemiarthroplasty procedures.

Devices for which Substantial Equivalence is claimed:

- Howmedica Osteonics Accolade II System: K103479
- Howmedica Osteonics Restoration Modular System: K013106
- Howmedica Osteonics Accolade TMZF: K994366, K020572 & K023102

Proposed Modification:
The subject Accolade II Hip stems are compatible with additional acetabular components.

Summary of Technologies: Device comparison showed that the proposed expanded compatibility of the device is substantially equivalent in intended use, materials and performance characteristics to the predicate devices. Engineering and risk analysis has been performed to demonstrate equivalence of the subject products to the predicate devices.

Clinical Testing: Clinical testing was not required for this submission.

Conclusion: The Accolade II Hip Stems are substantially equivalent to the predicate devices identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Howmedica Osteonics
% Ms. Valerie Giambanco
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325 Corporate Drive
Mahwah, New Jersey 07430

MAR 2 9 2012

Re: K120578
Trade/Device Name: Accolade II Hip Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: MEH, LZO, LWJ, KWZ, KWY, KWL, JDI, LPH
Dated: February 17, 2012
Received: February 28, 2012

Dear Ms. Giambanco:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

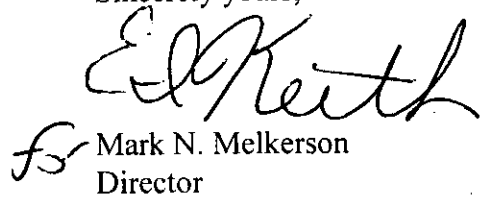
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120578

Device Name: Accolade II Hip Stem

Indications for Use:

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Accolade II Femoral Stems are intended for cementless use only and are intended for total and hemiarthroplasty procedures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120578